

## CLAIMS

1. A method for enhanced and controlled delivery of a biologically active agent into the spinal structures and/or the brain of a mammal, particularly a human being that circumvents the blood brain barrier, which includes the steps of:

providing an agent drug delivery device via catheter to the epidural space of the mammal and positioning said device within the epidural space,

advancing a donor iontophoresis electrode into the epidural space of the mammal,

applying a second electrode or receptor iontophoresis electrode that is constructed and arranged to be positioned at a determined internal or external position of the mammal's body but in complementary energy gradient positioning to the first electrode,

providing a potential gradient so that delivery of the biologically active agent is accomplished in a direction from said first electrode means directly into the spinal structures and/or the brain thereby essentially bypassing the blood brain barrier of the mammal; and thereby,

delivering said biologically active agent directly to the spinal structures and/or to the brain of said mammal

2. A method for enhanced and controlled delivery of a biologically active agent into the spinal structures and/or the brain of a mammal, particularly a human being that circumvents the blood brain barrier, which includes the steps of:

providing an agent drug delivery device via catheter to the epidural space of the mammal and positioning said device within the epidural space,

advancing a phonophoresis device in the epidural space of the mammal,

providing an energy gradient so that delivery of the biologically active agent is accomplished in a direction from said phonophoresis device directly into the spinal structures and/or the brain thereby essentially bypassing the blood brain barrier of the mammal, and thereby

delivering said biologically active agent to the spinal structures and/or to the brain of said mammal

3. Apparatus for enhanced and controlled delivery of a biologically active agent into the spinal structures and/or the brain of a mammal, particularly a human being that circumvents the blood brain barrier, comprising:

an agent drug delivery device implantable via catheter to the epidural space of the mammal ,

a donor iontophoresis electrode also implantable to the epidural space of the mammal,

a receptor iontophoresis electrode that is constructed and arranged to be positioned at a determined internal or external position of the mammal's body but in complementary energy gradient positioning to the first electrode,

means for providing a potential gradient so that delivery of the biologically active agent is accomplished in a direction from said first electrode means directly into the spinal structures and/or the brain thereby essentially bypassing the blood brain barrier of the mammal, and thereby

delivering said biologically active agent to the spinal structures and/or to the brain of said mammal

4. Apparatus for enhanced and controlled delivery of a biologically active agent into the spinal structures and/or the brain of a mammal, particularly a human being that circumvents the blood brain barrier, comprising:

an agent drug delivery device implantable via catheter to the epidural space of the mammal,

a phonophoresis device implantable to the epidural space of the mammal,

means for providing a potential gradient so that delivery of the biologically active agent is accomplished in a direction from said phonophoresis device directly into the spinal

structures and/or the brain thereby essentially bypassing the blood brain barrier of the mammal, and thereby

delivering said biologically active agent to the spinal structures and/or to the brain of said mammal

5. A method as claimed in claim 1 wherein a biosensor is used for feedback regulated delivery of the biologically active agent to the spinal structures and/or brain of the mammal.

6. A method as claimed in claim 5 wherein the biosensor is used for feedback regulated delivery of the biologically active agent in the treatment of chronic pain.

7. Apparatus as claimed in claim 3 wherein the donor electrode includes a drug reservoir or drug transfer part for storage of the biologically active agent, an impermeable part that is not involved in drug transfer, and an electroconductive member.

8. Apparatus as claimed in claim 3 wherein the donor electrode includes a means for expansion thereby allowing the drug reservoir or transfer part to make an intimate contact with the dura mater.

9. Apparatus as claimed in claim 8 wherein the expansion means is configured to expand the donor electrode in a direction substantially radial thereby promoting an improved contact interface between the drug reservoir or transfer part and the dura mater.

10. Apparatus as claimed in claim 9 wherein the expansion means is a balloon.

11. Apparatus as claimed in claim 8 wherein the expansion means is provided by reversible swelling properties of the drug reservoir or transfer part that is induced by chemical or physical changes such as for example, electric current, pH, temperature or any combinations thereof.

12. Apparatus as claimed in claim 8 wherein the drug delivery part of the device is shaped following expansion according to the human epidural space.

CITED REFERENCES:

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